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EXAMINER	
MEAH, MOHAMMAD Y	

ART UNIT	PAPER NUMBER
1652	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/581,294	PAUL ET AL.	
	Examiner	Art Unit	
	MD. YOUNUS MEAH	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 10-85* is/are pending in the application.

4a) Of the above claim(s) *2-5,34-70 and 75-85* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6-8,10-33 and 71-75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-8, 10-85 are currently pending in the instant application.

In response to a previous office action, a non-final action, mailed on 01/30/2009, Applicants' on 07/30/09 amended claim 1 and cancelled claim 9.

Applicants' response of 06/03/09 is acknowledged. Claims 1, 6-8, 10-33 and 71-75 are under consideration. Applicants' arguments filed on 07/30/09 have been fully considered but they are found unpersuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Applicants' argument about election/ restrictions considered. As explained before in the election/rejection office action 05/02/2008, claims are not linked by a special technical feature because the prior art (Taguchi et al. Biorg med. Chem. 2002, 12, 3167-3170) teaches applicants' covalently reactive polypeptide antigen pCRA (CRA of Taguchi et al). Applicants' argument about conformational flexibility of polypeptide covalently reactive antigen (pCRA) molecule is considered but found to be unpersuasive. Conformational flexibility of the pCRA and CRA antigens" is not considered a special technical feature, because the art teaches all the structural limitations of the pCRA antigen as well as the method of claim 1 as evidenced by the teachings of CRA of Taguchi et al. Therefore, the pCRA antigen of claim 1 has the "conformational flexibility" by virtue of having the recited structure, and since Taguchi et al. teach a CRA antigen having that same structure, Taguchi et al. teach this "conformational flexibility" technical feature.

Specification objection

The disclosure is objected to for reciting "transonic" in paragraphs 0100, 0103, 0486, 0559, 0560 and 0607. It should be replaced with "transgenic". Correction is required.

Objection

Claim 10 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 8. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 14 is objected in the recitation of "the polypeptide is gp120, VIP..." However, claim 1 refers to a polypeptide antigen, and claim 12 (depends from claim 1) refers to "polypeptide". There is no consistency in the use of "polypeptide antigen" and "polypeptide". It is suggested to the applicants to choose one or the other if the applicants intend them to be equivalent. If not, applicants should clearly make the distinction and amend the claims to explicitly indicate when applicants are referring to the polypeptide and when Applicants are referring to the polypeptide antigen. Appropriate correction is required.

Claim 18 is objected to for not reciting "and" before "e)" and not starting (e) in a different line. Appropriate correction is required.

Claims 15 and 38 are objected for reciting "transonic". It should be replaced with "transgenic". Correction is required

35 U.S.C 112 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 6-8, 10-33, and 71-75 (dependent on claim 1) remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons set forth below:

Claim 1 remain rejected and claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in reciting covalent antibodies as it is unclear what covalent antibodies is meant because claim 1 produce catalytic antibodies using pCRA, for examination purpose it is considered as catalytic antibodies. Applicants' amendment of claim 1 still indefinite because it is not clear whether "--covalent antibodies that form complexes with polypeptide antigens--" is covalently bound or not. It is suggested to amend the term to "--antibodies that form complexes with polypeptide antigens--"

Claim 6 is indefinite in the recitation of ""denaturant" as there is no antecedent basis for "denaturant" in claim 1, from which this claim depends. Does it mean the "protein denaturant" of claim 1?

Claim 6 is indefinite for following reason: Claim 6 depends on claim 1. Claim 1 requires the complexes not to dissociate on treatment with a protein denaturant. Claim 6 requires the binding of the antibodies to the antigen to be resistant to dissociation. Therefore claim 6 is broader in scope than claim 1 because claim 1 requires no dissociation whereas claim 6 simply requires "resistant to dissociation".

Claim 7 is indefinite for following reason: Claim 7 depends on claim 1. Claim 1 requires the complexes not to dissociate on treatment with a protein denaturant- Claim 7 requires the binding of the antibodies to the antigen to be resistant to dissociation. Therefore claim 7 is broader in scope than claim 1 because claim 1 requires no dissociation whereas claim 7 simply requires "resistant to dissociation".

Claim 13 is indefinite in the recitation of "the antigenic pCRA is the CRA derivative of gp120…" It is unclear what is the CRA derivative of the proteins recited. Do they follow formula 1? It is unclear how the term "CRA derivative" is related to the formula of (1).

Claim 18 is indefinite in the recitation of "single chain Fv fragments expressing covalent or catalytic activity. It is unclear how does a Fv fragment expresses these activities? It is unclear what is a covalent activity in relation to an Fv fragment?

Claim 14 is indefinite in the recitation of "the polypeptide" as there is no antecedent basis for "the polypeptide" in claim 12, from which this claim depends.

***Claim Rejections 35 U.S.C 112 1st* paragraph rejection**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6-7, 11-12, 15-23, 25-29, 71-75 remain rejected and amended claim 1 is rejected under 35 U.S.C. 112, first paragraph in the prior office action, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained as discussed at length in the previous office action and discussed it again below.

Claims 1, 6-7, 11-12, 15-23, 25-29, 71-75 are directed to a method of generating catalytic antibodies to a polypeptide covalently reactive antigen (PCRA) wherein said PCRA comprise any antigenic polypeptide covalently attached to any transition state analog of any reaction and injecting said antigen to any organism, wherein said antibodies produced show the catalytic activity of cleaving any peptide bond of any polypeptide. The prior art (Taguchi et al. *Biorg and Med chem. Lett.* 2002, 3167-3170) and the specification teach PCRAs (such as compounds in claims 30-33) that produce a catalytic antibody having protease activity. The specification (example 2, page 9) indicates that "A potential weakness is that immunogen does not contain structural

feature favoring synthesis of Abs capable of rapid hydrolysis of the acyl-Ab intermediate and product release". For the catalytic antibody reported in the specification, the serine protease-like catalytic activity for peptide-bonds is very low. The specification does not disclose how catalytic antibodies produced against any PCRA comprising any polypeptide epitope can catalyze the cleavage of any peptide bond of any antigenic polypeptide. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Applicants' are referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Applicants' arguments at pages 18 -22 of their amendment against the rejection of claims 1, 6-7, 11-12, 15-23, 25-29, 71-75 under 35 U.S.C. 112, first paragraph written description are acknowledged but are not found persuasive. Applicants argue that their methods are directed to generate catalytic antibodies to a serine protease type reaction. However claims 1, 6-7, 11-12, 15-23, 25-29, 71-75 are directed to a method of generating catalytic antibodies to a polypeptide covalently reactive antigen (PCRA) wherein said PCRA comprise any antigenic polypeptide covalently attached to any transition state analog of an enzymatic reaction that cleaves any peptide bond. As previously stated catalytic antibodies are generally made using transition state analogs that mimic the transition state of the reaction to be catalyzed. Some transition state

analogs or other hapten will produce catalytic antibodies and some will not, as discussed in an earlier action. The instant claims are drawn to catalytic antibodies produced against any PCRA comprising any polypeptide epitope and use said catalytic antibodies to cleave any peptide bond. The specification certainly does not teach any hapten having any polypeptide epitope that will produce such a catalytic antibody. Therefore, the rejection is maintained that one of ordinary skill in the art reading the instant specification would not conclude that applicant had possession of the claimed invention.

Claims , 6-7, 11-12,15-23, 25-29, 71-75 remain rejected and amended claim 1 is rejected under 35 U.S.C. 112, first paragraph, enablement requirement in the prior office action. This rejection is maintained as discussed at length in the previous office action and discussed it again below.

Claims 1, 6-7, 11-12,15-23, 25-29, 71-75 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for method of generating catalytic antibodies to the antigens of Fig. 37, 48 or 49 of the specification or compounds of claims 30-33, wherein said method comprises administering said PCRA to an organism such as a mouse and wherein said catalytic antibodies cleave the peptide bond of gp120 polypeptide, does not reasonably provide enablement for a method of generating a catalytic antibody that shows proteolytic activity against any peptide bond of any protein or polypeptide. Since production of catalytic antibodies

dependent on the structure of transition state analog (TS) (Mader et al.), and enzymatic reaction depends on the mimicking the TS of bond cleavage or formation of that reaction, and the specification does not teach the structures of all the constituents of the PCRA recited in the claims and hence, the TS of peptide bond cleavage reaction, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breath of the claim(s).

Claims 1, 6-7, 11-12, 15-23, 25-29, and 71-75 encompass a method of generating a catalytic antibody against a PCRA comprising any antigenic polypeptide covalently attached to any covalently reactive electrophilic group and administering said antigen in any organism and wherein said antibody catalyzes the cleavage of any peptide bond of any antigenic polypeptide or protein molecule. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of antigens and methods of generating catalytic antibodies

having any type of transition state (TS) that mimic the transition state of any peptide bond cleavage reaction of any polypeptide. These claims drawn to a method of generating catalytic antibody that catalyzes the cleavage of any peptide bond of any antigenic polypeptide or protein molecule. The prior art (Taguchi et al. *Biorg and Med chem. Lett.* 2002, 3167-3170) and the specification teach the production of catalytic antibodies against PCRAs of the compounds in claims 30-33 using transition state analogues. The specification or the prior art neither describes all the structures of the components of the PCRA nor teach how catalytic antibodies produced against said PCRA show cleavage of any peptide bond of any antigenic polypeptide or protein molecule. In view of the breadth of claims 1, 6-7, 11-12,15-29, 71-75, the amount of experimentation required to elicit antibodies and screening to isolate catalytic antibody molecules that shows the desired catalytic activity, i.e., the cleavage of any peptide bond of any antigenic polypeptide or protein molecule, and the lack of guidance, working examples, unpredictability of the art in predicting the function (catalytic activity) from protein's structure (Chica et al. Curr Opin Biotechnol. 2005 Aug; 16(4):378-84), the claimed invention would require undue experimentation. As such the specification fails to teach one of ordinary skill how to use the full scope of the claims.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use any catalytic antibody and method of making catalytic antibody by using PCRA comprising any peptide epitope wherein said catalytic antibodies show catalytic activity of any enzyme. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24

(CCPA 1970)). Without sufficient guidance, determination of PCRA having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Applicants' arguments, on pages 22-25 of their amendment, against rejection of claim 1, 6-7, 11-12,15-23, 25-29, 71-75 under 35 U.S.C 112, first paragraph enablement are acknowledged. Applicant argue that cleaving peptide bond of any polypeptide or protein using any catalytic antibody produced by any covalently reactive antigen (PCRA) is enabled because applicant teach rational design of some covalently reactive antigens (PCRA) which are capable to elicit catalytic antibodies that catalyzes peptide bond cleavage via a serine protease type reaction. This is not found to be true as explained above these claims drawn to method of generating catalytic antibody that shows catalytic activity of any enzymatic reaction of cleaving any peptide bond of any protein. As discussed above, the prior art and the specification teach certain transition state analogs of certain PCRAs such as the compounds in claims 30-33. The specification or the prior art neither describes all the structures of the components of the PCRA and nor teach how any catalytic antibody produced against any PCRA can show proteolytic activity against any peptide bond of any protein. In view of the breadth of claims 1, 6-7, 11-12, 15-29, 71-75, amount of experimentation required to elicit antibodies and screening to isolate catalytic antibody molecules that shows the desired catalytic activity of any catalytic activity of any reaction of peptide bond cleavage and the lack of guidance, working examples, the claimed invention would require undue

experimentation. As such the specification fails to teach one of ordinary skill how to use the full scope of the claims.

CLAIM Rejection - 35 U.S.C 102

35 U.S.C 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8-14 and 16, 24 and 31 remain rejected and amended claim 1 is rejected under 35 U.S.C. 102 (a) as being anticipated by Taguchi et al. (*Biorg and Med chem. Lett.* 2002, 3167-3170 , from IDS). This rejection is maintained as discussed at length in the previous office action and discussed it again.

Taguchi et al. teach catalytic antibody raised by using a gp120 polypeptide epitope (L of claim 1 having carboxyl functional group of amino acid residue as Y") attached covalently to phosphonate ester (Y reactive electrophilic group, Transition state analogue) which comprises a covalently reactive antigen (CRA) (page 3168 fig 1) and wherein said phosphonate ester moiety binds to the antibody and a method of producing said antibody by administering said CRA to a mouse (page 3168, column 1, pargh. 3).

Applicants' arguments presented at pages 26-28 of the response filed on 7/30/2009 traversing the instant 35 U.S.C. 102(b) rejection have been considered but not found to be persuasive because Taguchi et al. teach a catalytic antibody using a gp120 polypeptide epitope (L of claim 1 having carboxyl functional group of amino acid residue as Y") attached covalently to phosphonate ester (Y reactive electrophilic group, Transition state analogue) which comprises a covalently reactive antigen (CRA). Since claims 1, 8-14 and 16, 24 and 31 are directed to a method of generating catalytic antibodies against the antigen comprising the PCRA of formula 1 of claim 1; the teaching of Taguchi et al. anticipate applicant invention. Applicants' argument that Taguchi et al. do not teach the production of antibody using CRA of fig 1 of Taguchi et al. is not found to be persuasive because Taguchi et al. describe (page 3168, column 1, pargh. 3, Fig 2.) the production of antibodies in mouse using the antigen of Fig 1.

Claims 8-14, 16-18, 21-22, 24-29, 71-72 and 74 remain rejected and amended claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Paul et al. (US 6235714). This rejection is maintained as discussed at length in the previous office action and discussed it again below.

Paul et al. teach a catalytic antibody and a method of producing said antibody, (monoclonal or polyclonal, single chain Fv fragments, column 16 lines 48-66) by administering to an organism (MRL/lpr mouse, column 14 lines 45-60) a covalently reactive peptide antigen, CRAA (column 3 lines 25-45, CRAA is X1-Y--E-X2, wherein

X1, X2 peptide molecule having reactive functional group attached to E electrophonic reactive center that react covalently to a nucleophile, Y is a basic residue of the peptide molecule). CRRA of Paul et al. is identical to applicants' pCRA. Paul et al. also teach the said CRAA comprises polypeptide epitope attached covalently to phosphonate ester (Transition state analogue), figs 4, 10,15- 17 of US6235714). Paul et al. also teach that the antigen molecule comprises tumor necrosis factor, epidermal growth factor receptor, gp120 (claim 4), etc and state that catalytic antibodies produced against said antigens can be used for the treatment of medical disorders like cancer, autoimmune diseases (column 6, lines 1-13, and figures 19A-B)

Applicants' arguments presented at pages 29-30 of the response filed on 7/30/2009 traversing the instant 35 U.S.C. 102(b) rejection have been considered but not found to be persuasive because Paul et al. teach catalytic antibody and method of producing said antibody by administering to an organism a covalently reactive peptide antigen CRAA (X1-Y--E-X2). CRAA of Paul et al. is identical to applicants' pCRA of claim 1. Since claims 1, 8-14 and 16, 24 and 31 are directed to method of generating catalytic antibodies against the antigen comprising PCRA of formula 1 of claim 1; Paul et al. anticipate applicant invention. Applicants' argument that Paul et al. teach a CRAA comprising only 3-10 amino acids epitope is considered but found to be unpersuasive. Claim 1 of instant application comprises a pCRA (formula 1) comprising 4 or more amino acid residues.

Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 6-29, 71-75 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of US PAT 6855528. This rejection is maintained as discussed at length in the previous office action and discussed it again

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by,

or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 1, 6-29, 71-75 herein and claim 1 of the US PAT 6855528 are both directed to a method of generating catalytic antibodies to polypeptide covalently reactive antigen comprise any antigenic polypeptide attached with any reactive covalently attached active center by inducing said antigen in organism such as mouse. The portion of the specification of the US PAT 6855528 that supports the recited method of generating catalytic antibodies to polypeptide covalently reactive antigen comprising antigenic polypeptide attached with reactive covalently attached active center by inducing said antigen in any organism.

Claims 1, 6-29, 71-75 cannot be considered patentably distinct over claim 1 of the US PAT 6855528 when there is a specifically recited embodiment (i.e. method of stimulating production of catalytic antibodies to polypeptide covalently reactive antigen analog comprise antigenic polypeptide attached electrophilic group by inducing said antigen in organism) that would anticipate claims 1, 6-29, 71-75 herein. Alternatively, claims 1, 6-29, 71-75 herein cannot be considered patentably distinct over claim 1 of US PAT 6855528 when there is a specifically disclosed embodiment in US PAT 6855528 that supports claim 1 of that application. US PAT 6855528 teaches catalytic antibodies and method of producing said antibodies (monoclonal, polyclonal, Fv fragments, column 30, lines 11-51, column 31) using antigen PCRA (fig 2, 8, 16) wherein said antigen

bind to antibody that resistant to dissociation by 2% SDS (fig 11, column 29, line 20-27, column 30, lines 1-10). US PAT 6855528 also teach that PCRA antigen comprise GP120, tumor necrosis factor (claim 6) and catalytic antibodies produced can be used for treatment of cancer, autoimmune diseases (column 9, lines 24-31) or diseases directed to factor VIII (column 24, lines 35-51). Therefore these embodiments fall within the scope of claims 1, 6-29, 71-75 herein and it would have been obvious to one having ordinary skill in the art to select the specific antigen analog comprise any antigenic polypeptide attached with electrophilic group and used in the method of claim 1 of the US PAT 7338790 and the recited embodiments in the specification discussed above and pursue the inventions in the claims 1, 6-29, 71-75 of instant application. One having ordinary skill in the art would have been motivated to do this because that embodiment is disclosed as being a preferred embodiment within claim 1.

Applicants' arguments presented at pages 30-33 of the response filed on 7/30/2009 traversing the instant ODP rejection have been considered but not found to be persuasive because Paul et al. teach a catalytic antibody and a method of producing said antibody by administering a CRAA (X1-Y--E-X2, wherein X1, X2 peptide molecule having reactive functional group attached to E electrophonic reactive center that react covalently to a nucleophile, Y is a basic residue of the peptide molecule) to an animal such as mouse. CRRA of Paul et al. is identical to applicants' pCRA of claim 1. Applicants argument that Paul et al. teach CRAA comprising only 3-10 amino acids epitope is considered but found to be unpersuasive. Claim 1 of instant application

comprises the pCRA which comprises polypeptide epitope comprising 3-10 amino acids.

Conclusion

Claims 1, 6-8, 10-33 and 71-75 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mohammad Meah whose telephone number is 571-272-1261. The examiner can normally be reached on 8:30-5PM.
If attempts to reach the examiner by telephone are unsuccessful, the examiner's Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mohammad Younus Meah
Examiner, Art Unit 1652

/Delia M. Ramirez/
Primary Examiner, Art Unit 1652